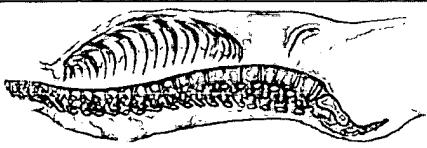


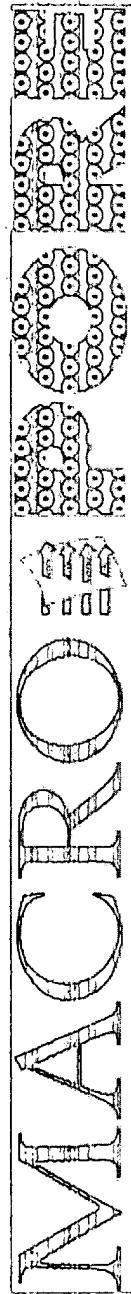
MacroPoreTM Bioresorbable Antithrombotic Film



GCB Gaynor Cornwall PhD Bill DuBois, Ken Kleinhennz

MacroPore, Inc.

March 2001



Advanced Resorbable Solutions

MacroPore TS:

Anti-Adhesion Film

- **RATIONALE:**

Scarring adjacent to the exiting nerve roots has been implicated in failed back syndrome.

- **STRATEGY:**

510(k) submitted: January 19, 2001*

*(this will not have the same indications as Gliatech - PMA)

- **MARKET SIZE:**

US

\$25+

EU

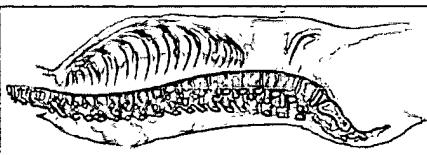
\$5

Japan

\$30+

Other

\$0



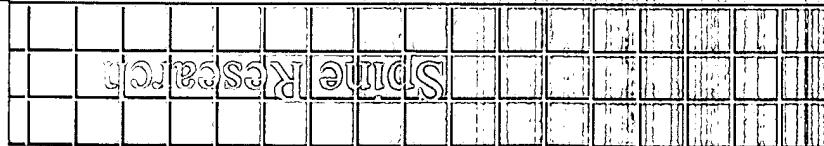
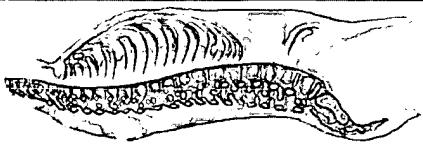
Some Regulators									
Regulator	US	EU	Japan	Other	Regulator	US	EU	Japan	Other
US	✓	✓	✓	✓	EU	✓	✓	✓	✓
EU	✓	✓	✓	✓	Japan	✓	✓	✓	✓
Japan	✓	✓	✓	✓	Other	✓	✓	✓	✓

MacroPore TS[®]

Indications for Use (submitted)

- 1) Surgical repair of fractured orbital floors
- 2) Surgical repair of nasal septum and perforated ear drum membrane
- 3) Used as a protective sheathing to facilitate osteogenesis
- 4) For surgical repair of urethral anatomy and repair of urethral strictures
- 5) To prevent synostosis in completed corrective surgery for cranial fusions and forearm fractures
- 6) Lesser soft-tissue fibrosis or bony growth
- 7) As a temporary covering for perineal surgical incisions

Not indicated for use in the treatment of malignant neoplasms or to prevent infection.

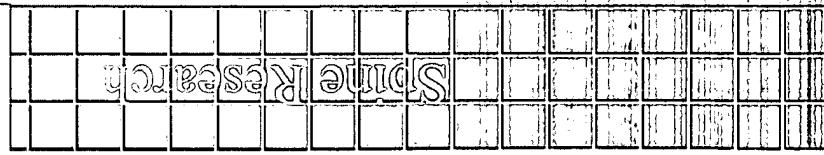
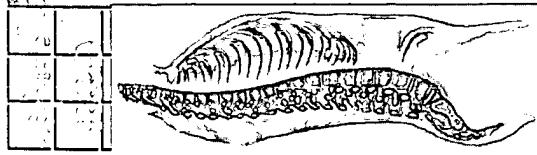


MacroPore TS[®]

Indications for Use (submitted)

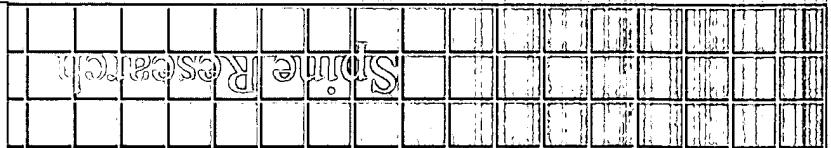
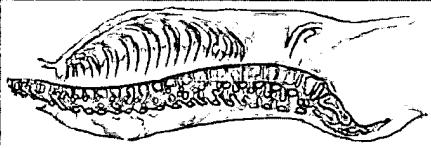
- 8) Guided tissue regeneration between the teeth and gingival margin
- 9) Tympanic membrane repairs
- 10) Dural coverings and neural repair
- 11) Tendon anastomosis
- 12) Temporary joint spacer
- 13) Wound dressings
- 14) Scar coverings
- 15) Covering for gastroschisis

(Not intended to be used when permanent implants are required.)

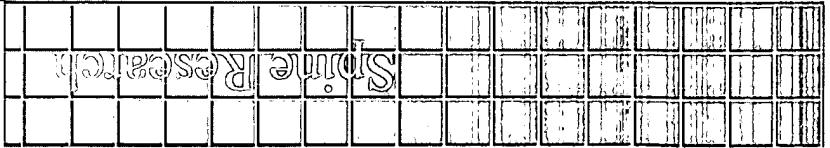


MacroPore TS: Anti-Adhesion Study

L5-L6 Laminectomy-Dura



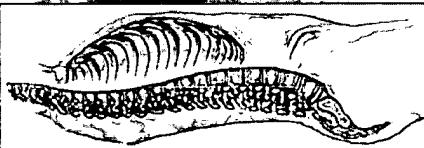
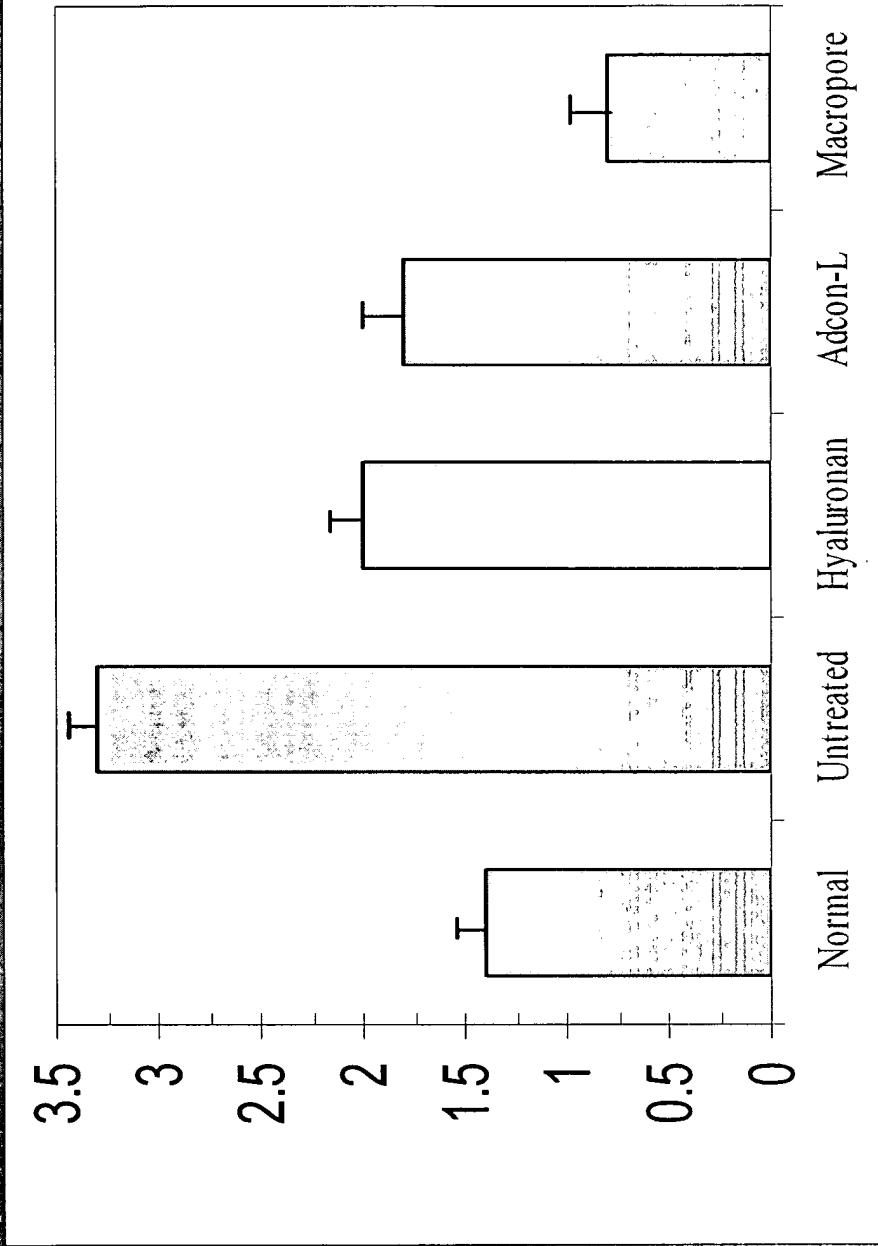
Simple Resorbable



MacroPore TS:

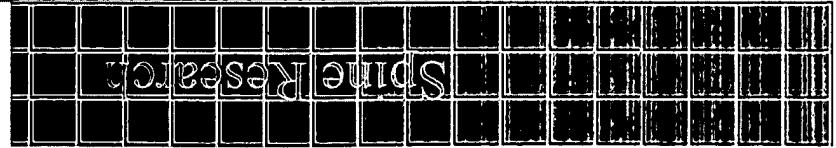
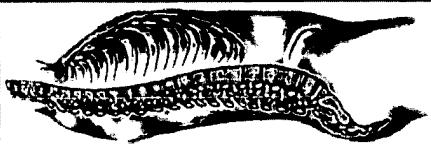
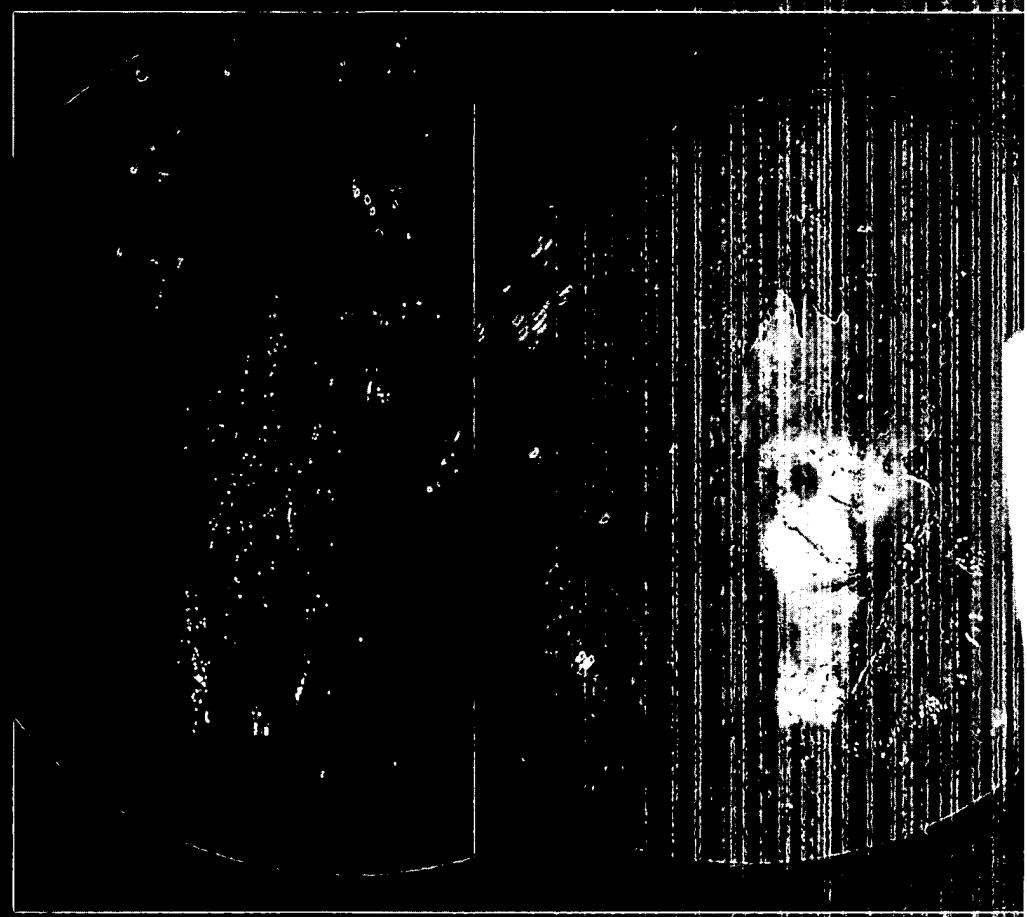
Anti-Adhesion Study

Total Collagen Content of Epidural Space



Macropore TS:

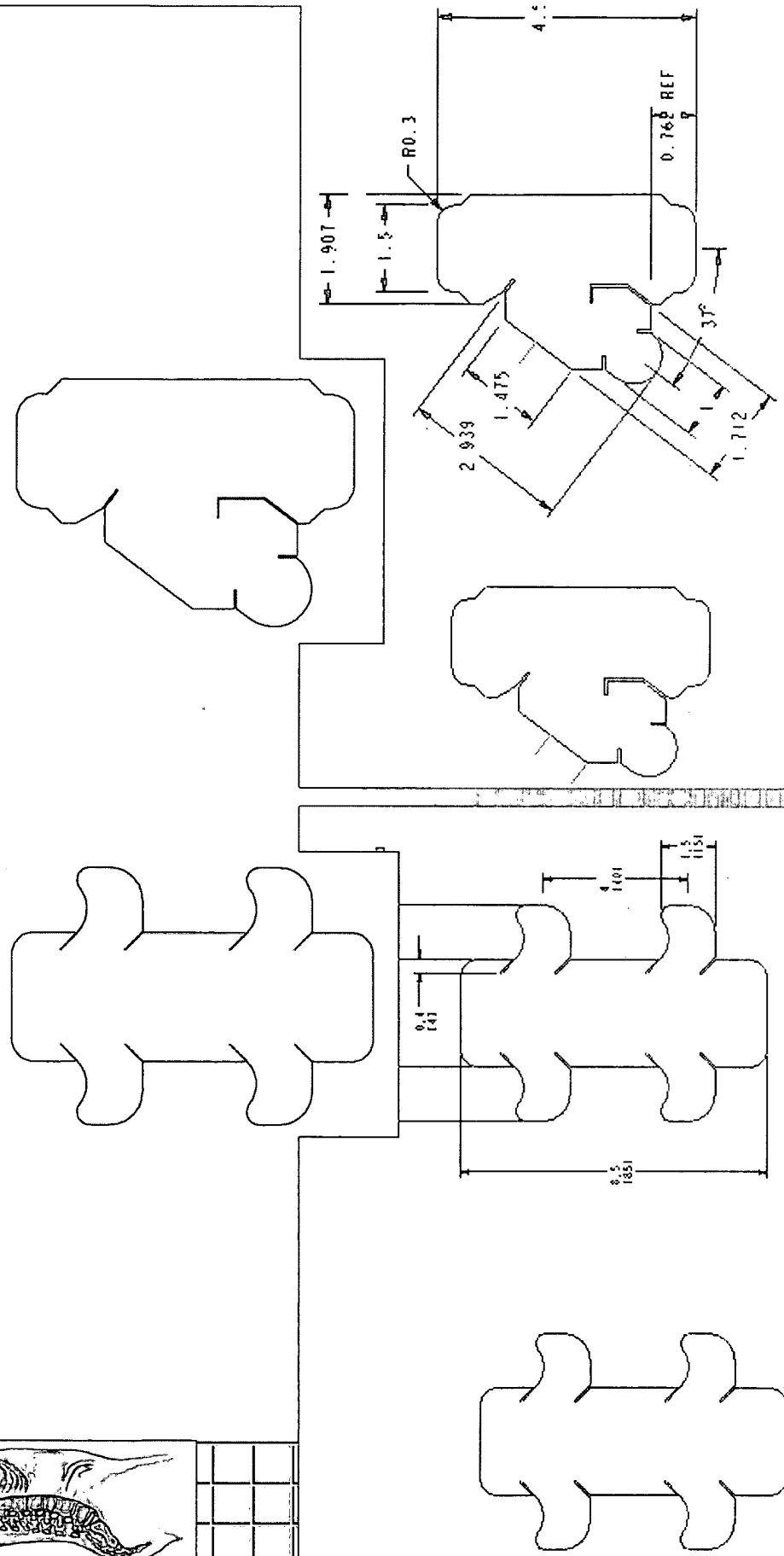
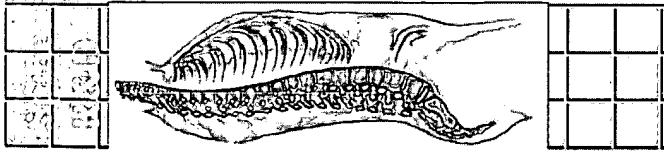
Anti-Adhesion Film



SPINE RESEARCH

MacroPore TS[®]

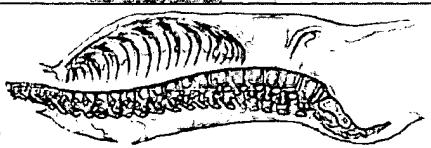
Anti-Adhesion Film



TYPE : PART NAME : 803-0003-REV-1 SIZE : A

TYPE : PART NAME : 803-0003-REV-1 SIZE : A

Literature Review



- The degradation of PLA implants does not seem to create any sinus formations or significant pH variance according to clinical data and animal testing
- Properly sterilized PLA does not appear to cause unusual infection or foreign body reaction
- PLA is more accepted by the body than PGA, another common biodegradable material

Conclusions

- o Early pre-clinical results (rat model) demonstrate quantitative reduction in collagen content – associated with scar.
- o PLA is a biocompatible & safe material.
- o Surgeon Interest & Excitement in this product is STRONG!

